

Enclosed herewith are the following Exhibits providing evidence of utility of the claimed process on animals and humans:

A) Animal Data

- 1) Proceedings of the Seventh International Congress of Pharmacology, Paris, 1978, "Advances in Pharmacology and Therapeutics", Volume 4, B.B. Vargaftig, Editor, Pergamon Press, pages 167 through 176.
- 2) "Adjuvant Treatment with Levamisole in Cancer; A Review of Experimental and Clinical Data", W.K. Amery, et al., Cancer Treatment Reviews (1977) 4, 167-194.

B) Human Data

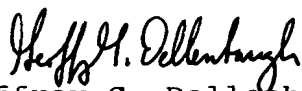
- 1) "Effects of Levamisole Treatment in Cancer Patients", W.K. Amery and H. Verhaegen, Journal of Rheumatology Supplement No. 4, 1978, pages 123-135.
- 2) "Updated Clinical Summary - 1980" in support of amended New Drug Application for levamisole in cancer treatment.

The enclosed Exhibits are believed to establish beyond a shadow of a doubt the utility of the claimed processes under 35 USC 101. Although a New Drug Application for the treatment of cancer with levamisole was filed on October 30, 1980, Applicants do not believe that they are required by 35 USC 101 to obtain approval of the Food and Drug Administration for the claimed methods as a condition for allowance of the subject claims. It is Applicants' position that the evidence enclosed herewith clearly establishes the utility not only of the newly-presented Claims 4 through 19, but also of the broader original Claims 1-3. Certainly with regard to the

newly-presented claims, the evidence of utility is overwhelming, particularly with regard to efficacy in humans.

The Examiner should note that these newly-presented claims are substantial duplicates of original Claims 1 and 2 but with the names of certain specific neoplastic diseases inserted in place of the general term "neoplastic disease". Support for these claims is found in the claims as filed and in the first paragraph on page 3 of the specification in which the term "neoplastic disease" is defined to include all types of cancerous growths or oncogenic processes, and the like.

Respectfully submitted,

  
Geoffrey G. Dellenbaugh  
Attorney for Applicants  
Registration No. 26,864

GGD/jt

501 George Street  
New Brunswick, N.J. 08903  
(201) 524-9323